DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier Romoni Clever

[Docket No. 00N–1604]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; OTC Test Sample Collection Systems for Drugs of Abuse Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

OTC Test Sample Collection Systems for Drugs of Abuse Testing—21 CFR Part 809 (OMB Control Number 0910–0368)—Extension

FDA has reclassified over-the-counter (OTC) test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) subject to restrictions established in accordance with section 520(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j)(e).

The labeling requirements for certain in vitro diagnostic products require that manufacturers of OTC test sample collection systems for drugs of abuse testing provide certain information to consumers for the proper use of the test sample collection system and for interpreting the results. The purpose of this regulation is to ensure that lay persons collecting samples for testing have adequate instructions for sample collection and handling and for receiving and understanding the test results reported by laboratories performing the analyses.

The most likely respondents to this information collection will be manufacturers of over-the-counter drugs of abuse test kits.

In the **Federal Register** of November 16, 2000 (65 FR 69314), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total Hours
809.10	20	1	20	100	2,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based upon submissions to the agency (premarket notifications, premarket approval applications, registration and listing), FDA estimates that there will be about 20 manufacturers of these devices.

FDA estimates, based upon discussions with manufacturers of similar devices required to comply with 21 CFR 809.10, that it will take approximately 40 hours to gather the information

required by the rule, 40 hours to design and prepare the labeling, and an additional 20 hours per year to review and revise the labeling as necessary.

Dated: February 2, 2001

William Hubbard

William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

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